IV. Remarks:

35 USC §102 Concerns:

Of course, for a reference to serve as a basis for a valid 35 USC §102 rejection, the reference must disclose each and every limit of the claim. As the examiner has rejected certain claims under 35 USC §102 as based on a patent issued to Lappe (US Pat. No. 6,036,092, hereinafter referred to as the Lappe patent, or simply Lappe), for such rejection to be valid, the Lappe patent must disclose each and every limit of a claim. However, the following are limits of claims rejected under §102 that the Lappe patent does not disclose, in addition to explanations of such non-disclosure:

Claim 1 (and dependents) - Response to 35 USC §102 Concerns:

- "*adequately specifying a specimen related event identifier*":

- Descriptive references to this limit of the instant application's claim 1:

- from par. [0056] of the publication of the instant application: "adequately specifying a specimen related event identifier (e.g., a specimen collection event identifier such as a time of collection)"

- from par. [0056] of the publication of the instant application: "The specimen related event identifier may be a time, a term that includes (a) merely a date such as a specimen collection date, (b) a date and an adequately specific time of day of specimen collection; and also (comprises) a year, perhaps that year during which the specimen collection took place. By adequately specific is meant specific enough to adequately identify the event so that, when used in conjunction with a specimen donor identification information item, the resultant information item will be sufficiently reliable to identify as desired. An adequately specific time of

day may thus merely be an indication as to AM or PM, or, at the other extreme, may need to be as detailed as 9:48PM, 52 seconds, with perhaps an indication as to fractions of a second, including any levels of specificity therebetween."

- *Why it is clear that the Lappe patent does not disclose this limit:*

- The Lappe reference does not disclose the limit "adequately specifying a specimen related event identifier." What it appears the Office considers a "specimen related event identifier" (see the reference to "col. 3, lines "4+" on page 2, section 6, of the office action) is actually not an event identifier at all (e.g., it is not a time indication), but rather is a "test result" (e.g., either positive or a negative) encoded via "bar code indicia" (again, please see col. 3, lines 4+ of the Lappe patent).

That the Lappe patent does not disclose this limit of claim 1 is entirely consistent with the focus of the Lappe patent, as summarized in column 5, lines 28-34: "Accordingly, this type of assaying system, wherein positive results are clearly apparent to a test administrator, posed great threats to individual privacy and civil liberty concerns, and hence is generally considered unsatisfactory. The employment of the assaying means by the present invention, however, addresses this, as well as other deficiencies."

It is of note that the Lappe patent does disclose an "identification code" (see, e.g., col. 6, lines 50-61 of the Lappe patent), but such code is used to identify the test card alone (e.g., its "date of manufacture", or its "production batch number[s]"), and as such is not "specimen related" as claim 1 requires. Further, the Lappe patent's reference to a "case code identifying the donor, such as a social security number in the case of a human donor...." (see col. 8, lines 42-47) is, admittedly, reference to a certain type of "specimen donor identification information item" as

appears in claim 1, but not reference to a "specimen related event identifier."

- "*associating said specimen donor identification information item with said specimen related event identifier*":

- As there is no disclosure in the Lappe patent of a "specimen related event identifier", there can be no disclosure of the step of "associating said specimen donor identification information item with said specimen related event identifier"

- "*generating a unique specimen identification information item in response to said step of associating said specimen donor identification information item with said specimen related event identifier*":

- As there is no disclosure in the Lappe patent of "associating said specimen donor identification information item with said specimen related event identifier", there can be no disclosure in the Lappe patent of the step of "generating a unique specimen identification information item in response to" such step. Indeed, it can even be said that there is no disclosure of a "unique specimen identification information item", as the "case code identifying the donor" merely identifies the donor and, as a donor can produce more than one specimen (whether during the same day or in different years, as referred to in Par. [0018] of the publication of the instant application), a "case code identifying the donor" does not constitute a "unique specimen identification information item".

Par. [0057] of the publication of the instant application (page 22, lines 10-24 of the application as filed) includes different examples of "unique specimen identification information items". Upon "associating said specimen donor identification information item with said specimen related

event identifier", a "unique specimen identification information item" may be generated; such information item may be of the form shown in Par. [0057]. Lappe, nor any other patent of which the Assignee is aware, simply does not disclose this.

It is also of note that the Office's consideration of the bar code 42 as a "unique specimen identification information item" (see office action, page 2, section 6) is, respectfully, incorrect, as it appears this bar code 42 is not a specimen identification information item at all, but instead is an encryption of identification information relative to a test result (either a positive or negative) and/or information related to the card itself (e.g., "production batch numbers of the test card, a date of manufacture [of the test card], the specific substances the test card is configured to detect, etc." (col. 6, lines 50-54 of Lappe)). This is also clear from the following passages of the Lappe patent: "The test result which is encoded within the bar code indicia located upon the test card is read by an appropriate test card reading apparatus..." (see col. 3, lines 5-10); "Therefore, only a suitable configured device, employed to decode the encoded bar code indicia, will be able to determine the results of the assay" (see col. 6, lines 22-24); and "As those skilled in the art will recognize, it is often desirable to have items such as production batch numbers of the test card, a date of manufacture, the specific substances the test card is configured to detect, etc." (col. 6, lines 50-54). Yes, the Lappe patent refers to its bar code as an "identification code 42", but as explained immediately above, the only 'things' identified are test result, and possibly also "production batch numbers of the test card, a date of manufacture [of the test card], the specific substances the test card is configured to detect, etc." (col. 6, lines 50-54). Thus, the bar code is clearly not a "unique specimen identification information item" as appears in claim 1 and as described in the instant application (again, see examples in Par. [0057] of the publication of the instant application).

Claim 35 (and dependents) - Response to 35 USC §102 Concerns:

- "*specimen related event identifier*":

The Assignee incorporates herein the above explanation relative to the non-disclosure of the "*adequately specifying a specimen related event identifier*" limit of claim 1.

- "*a specimen related event identifier associated with said specimen and appearing with said specimen donor identification information item so as to establish a specimen identifier*":

The Assignee incorporates herein the above explanation relative to the non-disclosure of the step of "*generating a unique specimen identification information item in response to said step of associating said specimen donor identification information item with said specimen related event identifier*" of claim 1.

The Assignee further adds that for a piece of prior art to disclose the subject matter of claim 35, it would need to disclose a "specimen related event identifier associated with [a] specimen and appearing with said specimen donor identification information item so as to establish a specimen identifier" (emphasis added). Please see paragraph [0057] of the publication of the instant application (page 22, lines 10-24 of the application as filed) for examples of different possible "specimen identifiers." Neither the Lappe reference, nor any other reference of which the Assignee is aware, discloses this subject matter.

35 USC §103 Concerns:

Examiner's Concerns: The Examiner expressed concern as to claims 4-6, 38-40, 69 and 108 as based on the Lappe patent (US Pat. No. 6,036,092) in view of a patent issued to

Ogden et al (US Pat. No. 4,871,077, hereinafter referred to as the Ogden patent, or simply Ogden).

Assignee's Response: In response, the Assignee explains as follows:

The Pending Claims as Amended are Not *Prima Facie* Obvious: Assignee first submits that those pending claims as to which the examiner expressed §103 concerns are not *prima facie* obvious. As the Examiner is well aware, "[T]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." MPEP 2142. The MPEP goes on to state that "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP 2143, Basic Requirements of a *Prima Facie* Case of Obviousness. Assignee submits that these three criteria can not be met with respect to 35 U.S.C §103 and explains its position as follows:

Claim 4 - Response to 35 USC §103 Concerns:

The prior art references, either alone or when combined, do not teach or suggest all the claim limitations, as they must for a *prima facie* case of obviousness to be established. Most notably, neither the Lappe patent, as explained above, nor the Ogden patent discloses claim 4's step of "generating a unique specimen identification information item in response to said step of associating said specimen donor identification information item with said specimen related event identifier." Of course, as the examiner is well aware, this is a limit of claim 4 because every dependent claim includes all the limits of the independent claim on which it is based (in addition to the limits of any intervening claims). Ogden's "sequential serial numbers" (see col. 8, lines 54-56) is not a "unique specimen identification information item" because such

sequential numbering may still result in the use of the same number to identify two entirely different specimens. This can occur where, as in Ogden apparently, no measures are taken to assure that different testing facilities that identify specimens according to a sequential numbering scheme do not use the same number. Indeed, this is one of the problems solved by the instant inventive technology, as indicated from the following passage of the instant application: "Further, given that there are currently no measures to assure that different entities that assign specimen or sample identification numbers (as but two examples, different testing laboratories or different collection sites) are using the same sample identification number for a different sample (whether that sample be from a different person or given at a different time by the same person), the current system is not without risk of some error stemming from the use of the same sample identification number for a different sample." (see p. 9, line 28 - p. 10, line 2 of the application as filed). Ogden does not disclose a "unique specimen identification information item" and it most certainly does not disclose the step of "generating a unique specimen identification information item in response to said step of associating said specimen donor identification information item with said specimen related event identifier."

It is of note that, as to claim 4 and, indeed, every other claim as to which the Office expressed an obviousness concern, a *prima facie* case cannot be established by the Office also because of the absence of "some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings", and from an absence of a "reasonable expectation of success." (MPEP 2143, Basic Requirements of a *Prima Facie* Case of Obviousness).

Claim 5 - Response to 35 USC §103 Concerns:

The prior art references, either alone or when combined, do not teach or suggest all the claim limitations, as they must for a *prima facie* case of obviousness to hold. Most notably, neither the Lappe patent, as explained above, nor the Ogden patent, as explained immediately above, discloses claim 5's step of "generating a unique specimen

identification information item in response to said step of associating said specimen donor identification information item with said specimen related event identifier."

Claim 6 - Response to 35 USC §103 Concerns:

The prior art references, either alone or when combined, do not teach or suggest all the claim limitations, as they must for a *prima facie* case of obviousness to be established. Most notably, neither the Lappe patent, as explained above, nor the Ogden patent as explained above, discloses claim 6's step of "generating a unique specimen identification information item in response to said step of associating said specimen donor identification information item with said specimen related event identifier."

Claim 38 - Response to 35 USC §103 Concerns:

The prior art references, either alone or when combined, do not teach or suggest all the claim limitations, as they must for a *prima facie* case of obviousness to be established. Most notably, neither the Lappe patent, as explained above, nor the Ogden patent discloses claim 38's limit of "a specimen related event identifier associated with said specimen and appearing with said specimen donor identification information item so as to establish a specimen identifier." As pointed out in an analogous explanation provided above relative to claim 4, the Ogden patent does not disclose "a specimen related event identifier associated with said specimen and appearing with said specimen donor identification information item so as to establish a specimen identifier" of claim 38.

Claim 39 - Response to 35 USC §103 Concerns:

The prior art references, either alone or when combined, do not teach or suggest all the claim limitations, as they must for a *prima facie* case of obviousness to be established. Most notably, neither the Lappe patent, as explained above, nor the Ogden patent, as explained immediately above, discloses claim 39's limit of "a specimen related

event identifier associated with said specimen and appearing with said specimen donor identification information item so as to establish a specimen identifier."

Claim 40 - Response to 35 USC §103 Concerns:

The prior art references, either alone or when combined, do not teach or suggest all the claim limitations, as they must for a *prima facie* case of obviousness to be established. Most notably, neither the Lappe patent, as explained above, nor the Ogden patent as explained above, discloses claim 40's limit of "a specimen related event identifier associated with said specimen and appearing with said specimen donor identification information item so as to establish a specimen identifier."

Claim 69 - Response to 35 USC §103 Concerns:

The prior art references, either alone or when combined, do not teach or suggest all the claim limitations, as they must for a *prima facie* case of obviousness to be established. Most notably, neither the Lappe nor the Ogden patent as explained, in analogous fashion above relative to claim 4, discloses the step of "generating a unique element identification information item in response to said step of associating said entity identification information item with said time-related identifier" as appears in claim 69. Quite simply, there is no disclosure in either Lappe or Ogden of the step of "generating a unique element identification information item" (again, a "unique element identification information item" may be as shown in Par. [0057] as shown in the publication of the instant application).

Claim 108 - Response to 35 USC §103 Concerns:

The prior art references, either alone or when combined, do not teach or suggest all the claim limitations, as they must for a *prima facie* case of obviousness to be established. Most notably, neither the Lappe nor the Ogden patent, as explained in analogous fashion above relative to claim 38, discloses the step of "a time related

identifier associated with said element and appearing with said entity identification information item so as to establish an element identifier" as appears in claim 108. Quite simply, there is no disclosure in either Lappe or Ogden of "a time related identifier associated with said element and appearing with said entity identification information item so as to establish an element identifier" ("element identifiers" may be as shown in Par. [0057] as shown in the publication of the instant application).

V. Conclusion:

The specification and claims have been amended to correct errors apparent in the initial application. Claims 1-69 and 108 remain in the application at this time and are believed to be in condition for allowance. An early consideration of the present application is earnestly requested.

Dated this 10th day of January, 2007.

Respectfully submitted,

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